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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,013	10/07/2003	Lawrence M. Kauvar	388512010900	6212

25225 7590 05/17/2004

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,013	KAUVAR ET AL.	
	Examiner	**Art Unit**	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-6* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the invention is not descriptive. The abstract should be a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative. The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

A preliminary examination of this application reveals that it includes terminology which is so different from that which is generally accepted in the art to which this invention pertains. For example: on page 5, paragraph [0018]:

> Thus, any convenient label may be used, depending on the partner to which the label it [sic] intended to be bound. Convenient labels include antibodies or fragments thereof, including recombinantly produced antibodies such as Fv antibodies, fragments such as Fab fragments, and the like. Ligands for particular receptors may be particularly useful. Peptides and peptidomimetics, aptamers, oligonucleotides desired to hybridize or bind through triplex formation, or any moiety which is the counterpart of a specific binding partner to be detected may be used as a label.

Typically, a label is a substance that is readily detected and is used for identification purposes. In immunoassays, labels are generally enzymes, radionuclides, colloidal metallic substances, fluorescent molecules, etc. Antibodies and fragments are generally not considered to be labels. Furthermore, the specification also appears to use labels interchangeably to mean both antibodies and signal generating moieties, such as fluorophores.

Applicants are required to provide a clarification of these matters or correlation with art-accepted terminology so that a proper comparison with the prior art can be made.

Applicants should be careful not to introduce any new matter into the disclosure (i.e. matter that is not supported by the disclosure as originally filed).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is vague and indefinite with respect to the description of the labels and the particulate support, as well as the signal generating moiety. The recitation of "each different label" in line 2 is confusing since it is unclear if it refers to the "particulate different labels" referenced in line 1. Also, in line 4, it is unclear what is meant by "standardized intensity."

Claim 1 is also confusing because it recites a multiplicity of different particulate labels, each comprising a particulate support coupled to at least two different signal generating moieties. The first signal generating moiety generates a signal that characterizes the label, and the second signal generating moiety is a standardized intensity. The labels further contain a specific binding reagent.

The recitation of a particulate label encompasses colloidal metallic particles as well as latex particles and carbon particles, which are conventional particulate labels. Therefore, the recitation that these "particulate labels" comprise a particulate support is redundant.

The recitation that the particulate support is coupled to at least two different signal generating moieties lacks antecedent support in the specification. The specification at pages 1 and 7 discloses particulate labels containing signal generating moieties such as a red wavelength emitting fluorophore and a blue wavelength emitting fluorophore in different ratios generating particulate labels with different hues. The specification does not teach coupling (i.e. surface coupling) of signal generating moieties to a particulate support to generate particulate labels.

In Claim 2, the recitation of "other(s)" is indefinite because it is unclear what labels or moieties are encompassed by "other(s)."

In Claim 3, the recitation of "the detection space" lacks antecedent support. Claims 3 is also vague and indefinite because it appears to lack a correlation between the detection step with the preamble of the claim. What exactly is the purpose of this method?

Claims 5 and 6 contain grammatical errors that render both claims indefinite. In claims 5 and 6, the recitation of "the collection of targets" lacks antecedent support. In claim 6, it is unclear what is meant by "the collection of targets constitutes neural circuitry."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 USC 102(b) as being anticipated by Han et al. 19 NAT. BIOTECHNOL. 631 (Jul. 2001).

With respect to claim 1, Han et al. teach a composition comprising a multiplicity of particulate labels (See Fig. 1(B)) having a particulate support (See Fig. 1(A), "polymer microbeads") to which is coupled a characterizing signal-generating moiety (See Fig. 1(A), "multicolor quantum dots" for measuring "relative intensity ratios" at different wavelengths) generating a visible signal ("optical readout"), and a standardized signal-generating moiety (See Fig. 1(A), "multicolor quantum dots" for measuring "absolute intensity" at different wavelengths). The wavelength of the standardized signal-generating moiety is different (See Fig. 1(A), "different wavelengths") from the wavelength of the characterizing signal-generating moiety. All the particulate supports generate the same signal (See p. 633, col. 2, lines 11-14) from the standardized signal-generating moiety. Finally, Han et al. teach a particulate label having a reagent (See Fig. 1(A), "Molecular probes (A-E)") for interaction with a desired target.

With respect to claim 2, Han et al. teach a characterizing signal-generating moiety comprising at least two signal-generating moieties (See Fig. 1(A), "multicolor quantum dots") generating different signals (See Fig. 1(A), "different wavelengths") wherein the magnitude of each signal is varied (See Fig. 1(A), "relative intensity ratios" at different wavelengths) among different labels (See Fig. 1(A), five different microbeads) to produce different hues (See Fig. 4).

With respect to claim 3, Han et al. teach a method of contacting an environment to view a pattern of labels (See p. 631, col. 1, lines 26-30) and a method of assessing the number of particulate labels associated with a detection space (See Fig. 3(A) and p. 632, col. 2, lines 23-40).

With respect to claim 4, Han et al. teach a method for viewing by microscopy (See Figs. 2 and 4(A)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5 and 6 are rejected 35 U.S.C. 103(a) as being unpatentable over Han et al. (19 NAT. BIOTECHNOL. 631 (Jul. 2001)) in view of Kauvar et al. (US 2001/0044116).

Han et al. teach a method of contacting an environment to view a pattern of particulate labels as substantially described *supra*. Han et al. do not teach a method of contacting intracellular environments or neural circuitry environments.

However, Kauvar et al. disclose a method using microscopy (See Fig. 1) to view intracellular targets (See p. 6, para. [0062], "cell or dendrites") or neural circuitry (See p. 6, para. [0062], "dendrites"). Therefore, it would have been obvious for a person of ordinary skill in the art to combine the method of contacting an environment to view a pattern of particulate labels of Han et al. with the method of using microscopy to view intracellular targets or neural circuitry of Kauvar et al. to provide a method of viewing a pattern of particulate labels in an intracellular or neural circuitry environment.

A skilled artisan would have had a reasonable expectation of success in using the labels of Han et al. in a method for viewing an intracellular environment because Han et al. teach that the use of multicolor optical coding using luminescent QDs offers important advantages and applications that are not possible with other types of dyes (Han et al., p. 631, col. 2, lines 32 through page 632). Han et al. also teach that by using their labels, particulate beads can be quantified based on the observed number of quantum dots, i.e. intensity multiplexing.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
5/14/04